Attorney Docket No.: LP-31004-US PATENT

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO. PCT/DK04/000573

US APPLN. SER. NO.: 10/569862

INTERNATIONAL FILING DATE: 30 August 2004

PRIORITY DATE: 29 August 2003

TITLE: MODIFIED RELEASE COMPOSITIONS COMPRISING

TACROLIMUS

APPLICANT(S) FOR RO/US: HOLM, Per and NORLING, Tomas

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

U.S. Patent Documents

Yamanaka et al., US Patent No. 6,387,918 B2, issued May 14, 2002

Foreign Patent Documents

Pharotech A/S WO 03/004001 A1, published January 16, 2003*

Lipocine, Inc. WO 01/37808 A1, published May 31, 2001*

Fujisawa Pharmaceutical Co., LTD EP 1 064 942 A1, published January 3, 2001*

Fujisawa Pharmaceutical Co., LTD EP 0 444 659 A2, published September 4, 1991

Fujisawa Pharmaceutical Co., LTD EP 0 184 162 A2, published June 11, 1986

Other Documents

Nishi et al., 2004, "The colon displays an absorptive capacity of Tacrolimus", Transplantation Proceedings, vol. 36, no. 2, pp. 364-366.*

Nishi et al., 2004, "The expression of intestinal CYP3A4 in the Piglet Model", Transplantation Proceedings vol. 36, no. 2, pp. 361-363.*

Sano et al., 2002, "Oral FK 506 blood levels are elevated in pig short bowel model: Further investigations with co-administration of an intestinal CYP3A4 inhibitor" Transplantation Proceedings vol. 34, no. 3, pp. 1050-1051.*

Honbo et al., 1987, "The oral dosage form of FK-506", Transplantation Proceedings, vol. 19, no. 5 supplement 6, pp. 17-22.*

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

The Information Disclosure Statement submitted herewith is being filed

- [x] before the mailing date of a first Office Action on the merits
- [] after the mailing date of a first Office Action on the merits. Please charge the fee of \$180 to credit card. Form PTO-2038 is attached.
- [x] An International Search Report is enclosed. References cited in the International Search report are asterisked.

Respectfully submitted,

Date: 6/13)06

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Substitute for form 1449/PTO				Complete if Known			
				Application Number	10/569862		
IN	IFORMATION	ı nı	SCI USIIDE	Filing Date	February 27, 2006		
				First Named Inventor Holm			
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Sheet	1	of	1	Attorney Docket Number	LP-31004-US		

				DOCUMENTS		
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		US- 6 207 049 DO	05 14 2002	Vemanaka et al		
		^{US-} 6,387,918 B2	05-14-2002	Yamanaka, et al.		
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		FORE	IGN PATENT DOCU	IMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ ⁶
		WO 03/004001 A1	01-16-2003	Pharotech A/S		
·		WO 01/37808 A1	05-31-2001	Lipocine, Inc.		
		EP 1 064 942 A1	01-03-2001	Fujisawa Co. LTD	,	
		EP 0 444 659 A2	09-04-1991	Fujisawa Co. LTD		
		EP 0 184 162 A2	06-11-1986	Fujisawa Co. LTD		

Examiner	Date	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO				Complete if Known		
				Application Number	10/569862	
INF	ORMATIO	N DIS	CLOSURE	Filing Date	February 27, 2006	
STA	STATEMENT BY APPLICANT			First Named Inventor	Holm	
	(lise as many s	hoote ae n	ecessary)	Art Unit	TBD	
(Use as many sheets as necessary)				Examiner Name	TBD	
Sheet	1	of	1	Attorney Docket Number	LP-31004-US	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		NISHI et al., 2004, "The colon displays an absorptive capacity of Tacrolimus", Transplantation Proceedings, vol. 36, no. 2, pp. 364-366.*	
		NISHI et al., 2004, "The expression of intestinal CYP3A4 in the Piglet Model", Transplantation Proceedings vol. 36, no. 2, pp. 361-363.*	
		SANO et al., 2002, "Oral FK 506 blood levels" Transplantation Proceedings vol. 34, no. 3, pp. 1050-1051.*	
		HONBO et al., 1987, "The oral dosage form of FK-506", Transplantation Proceedings, vol. 19, no. 5 supplement 6, pp. 17-22.*	

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